K032042

SEP 2 9 2003

sds Ormco
SYBRON DENTAL SPECIALTIES

Section III - 510(k) Summary of Safety and Effectiveness

Submitter:

Sybron Dental Specialties, Inc.
1717 W. Collins Avenue
Orange, California 92867
(714) 516-7484 - Phone
(714) 516-7488 - Facsimile
Colleen Boswell - Contact Person

Date Summary Prepared: June 2003

Device Name:

- Trade Name – *EnVision*
- Common Name – Orthodontic Bonding Adhesive
- Classification Name – Bracket Adhesive Resin and Tooth Conditioner, per 21 CFR § 872.3750

Devices for Which Substantial Equivalence is Claimed:

- 3M Unitek Dental Products Division, *Transbond XT*
- Reliance Orthodontic Products, Inc., *Light-Bond*

Device Description:

The device is a chromatic orthodontic bonding adhesive. This single paste bonding adhesive initially has a blue color that enhances ease of use. Upon curing, the final color takes on the shade of the tooth, rendering it unnoticeable. *Envision* has an extended working time and has a very fast light cure property that achieves high strength, allowing active archwires to be placed immediately. *EnVision* is compatible with traditional etching and sealant procedures, as well as newer self-etching techniques

Intended Use of the Device:

The intended use of *EnVision* is as a light-cured orthodontic bonding adhesive that is designed to be used for the attachment of orthodontic appliances to teeth.

Substantial Equivalence:

EnVision is substantially equivalent to other legally marketed devices in the United States. *EnVision* functions in a manner similar to and is intended for the same use as the products *Transbond XT* and *Light-Bond* cleared for marketing for 3M Unitek Dental Products Division and Reliance Orthodontic Products, Inc., respectively.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 2 9 2003

Mr. Colleen Boswell
Director, Corporation Compliance
Sybron Dental Specialties, Incorporated
1717 West Collins Avenue
Orange, California 92867

Re: K032042
Trade/Device Name: Envision
Regulation Number: 872.3750
Regulation Name: Bracket Adhesive Resin and Tooth Conditioner
Regulatory Class: II
Product Code: DYH
Dated: June 23, 2003
Received: July 1, 2003

Dear Mr. Boswell:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4613. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Susan Runner

Susan Runner, DDS, MA
Interim Director
Division of Anesthesiology, General Hospital
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Section I

Indications for Use Statement

Ver 3 - 4/24/96

Applicant: Ormco Corporation

510(k) Number (if known): K 032042

Device Name: EnVision

Indications For Use:

EnVision is a light-cured orthodontic bonding adhesive that is designed to be used for the attachment of orthodontic appliances to teeth.

for MSR

(Division Sign-Off)
Division of Anesthesiology, General Hospital,
Infection Control, Dental Devices

510(k) Number: K 032042

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Per 21 CFR 801.109)
(Optional Format 1-2-96)